

07/29/03
16711 U.S. PTO

PATENT

Attorney's Dock t No.: U 014740-4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

03508 U.S. PTO
10/629198
07/29/03

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of Inventors:

1. YEN-LIN CHEN
2. ING-ER HWANG
3. MING-CHIN LIN
4. CHIEN-CHO CHEN
5. GWO-FUNG YUAN

WARNING: The Declaration must name all of the actual inventor(s).

For (title):

MONASCUS PURPUREUS MUTANTS AND THEIR USE IN PREPARING FERMENTATION
PRODUCTS HAVING BLOOD PRESSURE LOWERING ACTIVITY

1. Type of Application

This new application is for a(n) (check one applicable item below):

- ☒ Original (nonprovisional)
☐ Design
☐ Plant

WARNING: Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4) unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date JULY 29, 2003 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EV327549117 addressed to the: Assistant Commissioner of Patents, Washington, D.C. 20231

JENNIFER RASHKIN

(type or print name of person mailing paper)


(Signature of person mailing paper)

NOTE: Each paper or fee referred to as enclosed herein has the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 CFR 1.10(b).

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 CFR 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

WARNING: Do not use this transmittal for the filing of a provisional application.

2. Ben fit of Prior U.S. Application(s) (35 U.S.C. 119(e), 120, or 121)

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

WARNING: When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional **must** be filed prior to the Saturday, Sunday or Federal holiday within the District of Columbia. See 37 C.F.R. § 1.78(a)(3).

- ☐ The new application being transmitted claims the benefit of prior U.S. application(s) and enclosed are **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

NOTE: If one of the following 3 items apply, then complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED** and a **NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION**.

- ☐ Divisional.
☐ Continuation.
☐ Continuation-in-Part (C-I-P).

3. Papers Enclosed That Are Required For Filing Date Under 37 CFR 1.53 (Regular) or 37 CFR 1.153 (Design) Application

12 Pages of specification

3 Pages of claims

1 Pages of Abstract

 Sheets of drawing

- ☐ formal
☐ informal

WARNING: **DO NOT** submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page." 37 C.F.R. 1.84(c).

(complete the following, if applicable)

- ☐ The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)". 37 C.F.R. 1.84(b).

4. Additional papers enclosed

- ☒ Preliminary Amendment
- ☒ Information Disclosure Statement (37 CFR 1.98)
- ☒ Form PTO-1449
- ☒ Citations
- ☒ Declaration of Biological Deposit
- ☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
- ☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative
- ☐ Special Comments
- ☐ Other

5. Declaration or oath

- ☒ Enclosed
- executed by (*check all applicable boxes*)
- ☒ inventors.
- ☐ legal representative of inventors. 37 CFR 1.42 or 1.43
- ☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.
- ☐ This is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached. *See item 13 below for fee.*
- ☐ Not Enclosed.

WARNING: *Where the filing is a completion in the U.S. of an International Application but where a declaration is not available or where the completion of the U.S. application contains subject matter in addition to the International Application the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.*

- ☐ Application is made by a person authorized under 37 CFR 1.41(c) on behalf of *all the above named inventors*. (The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently).

NOTE: *It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b).*

- ☐ Showing that the filing is authorized. (*Not required unless called into question. 37 CFR 1.41(d).*)

6. Inventorship Statement

WARNING: *If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.*

The inventorship for all the claims in this application are:

- ☐ The same
- ☐ Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. A verified English translation of the non-English language application and the processing fee of \$130.00 required by 37 CFR 1.17(k) is required to be filed with the application or within such time as may be set by the Office. 37 CFR 1.52(d).

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).

☒ English

☐ non-English

☐ the attached translation is a verified translation. 37 CFR 1.52(d).

8. Assignment

☒ An assignment of the invention to FOOD INDUSTRY RESEARCH AND DEVELOPMENT INSTITUTE

☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

☒ will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters—one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: A newly executed "CERTIFICATE UNDER 37 CFR 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993. 1150 O.G. 62-64.

9. Certified Copy

Certified copy of application

Country	Appl. No.	Filed
Taiwan	091118398	August 15, 2002

from which priority is claimed

☒ is attached.

☐ will follow.

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 CFR 1.16)

A. ☒ Regular Application

Claims as Filed

Number Filed	Number Extra	Rate	Basic Fe 37 CFR 1.16(a) \$750.00
Total Claims (37 CFR 1.16(c))	26 - 20 = 6 x \$	18.00	108.00
Independent Claims (37 CFR 1.16(b))	1 - 3 = 0 x \$	84.00	
Multiple dependent claim(s), if any (37 CFR 1.16(d))	+ \$	280.00	

- ☐ Amendment cancelling extra claims enclosed.
- ☐ Amendment deleting multiple-dependencies enclosed.
- ☐ Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation \$ 858.00

- B. ☐ Design application
(\$330.00 — 37 CFR 1.16(f))

Filing Fee Calculation \$

- C. ☐ Plant application
(\$520.00 — 37 CFR 1.16(g))

Filing Fee Calculation \$

11. Small Entity Statement(s)

- ☒ Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is(are) attached or has been filed.

Filing Fee Calculation (50% of A, B or C above) \$ 429.00

NOTE: Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee. 37 CFR 1.28(a).

12. Request for International-Type Search (37 CFR 1.104(d)) (Complete, if applicable)

- ☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made At This Time

- ☐ Not Enclosed
- ☐ No filing fee is to be paid at this time. (This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)

- ☒ Enclosed

☒ basic filing fee \$ 429.00

- ☐ Recording assignment
(\$40.00; 37 CFR 1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION.")
- ☐ Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached.
(\$130.00; 37 CFR 1.47 and 1.17(h)) \$
- ☐ For processing an application with a specification in a non-English language.
(\$130.00; 37 CFR 1.52(d) and 1.17(k)) \$
- ☐ Processing and retention fee
(\$130.00; 37 CFR 1.53(d) and 1.21(l))
- ☐ Fee for international-type search report
(\$40.00; 37 CFR 1.21(e)). \$

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78, indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid or the processing and retention fee of §1.21(l) must be paid within 1 year from notification under §53(d).

Total fees enclosed \$ 429.00

14. Method of Payment of Fees

- ☒ Check in the amount of \$ 429.00
 - ☐ Charge Account No. 12-0425 in the amount of \$
- A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

- ☒ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 12-0425.
 - ☒ 37 CFR 1.16(a), (f) or (g) (filing fees)
 - ☐ 37 CFR 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

- ☐ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
- ☒ 37 CFR 1.17 (application processing fees)

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under §1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 C.F.R. 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27)

- ☒ 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application ... prior to paying, or at the time of paying, ... issue fee". From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions As To Overpayment

- ☒ credit Account No. 12-0425
☐ refund



Signature of Attorney

Reg. No. 25,858

Tel. No. (212) 708-1945

William R. Evans
Ladas & Parry
26 West 61 Street
New York, NY 10023

☐ **Incorporation by reference of added pages**

(Check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

- ☐ Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added ____

- ☐ Plus Added Pages for Papers Referred to in Item 4 Above

Number of pages added ____

- ☐ Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added ____

☒ **Statement Where No Further Pages Added**

(If no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item:)

- ☒ This transmittal ends with this page.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: YEN-LIN CHEN, ET AL.

Filed: JULY 29, 2003

For: *MONASCUS PURPUREUS* MUTANTS AND THEIR USE IN PREPARING
FERMENTATION PRODUCTS HAVING BLOOD PRESSURE LOWERING
ACTIVITYCommissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF BIOLOGICAL CULTURE DEPOSIT

WARNING: Submission of a letter related to a biological deposit after a Notice of Allowance may subject an application to a reduction in patent term adjustment under 37 C.F.R. 1.704(c)(10). See Notice of May 29, 2001, 1247 OG 111-112, June 26, 2001.

I, WILLIAM R. EVANS
Name of Applicant or Assignee or Assignee's representative

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is **mandatory**;
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. SECTION 1.8(a)

☐ with sufficient postage as first class mail.

37 C.F.R. SECTION 1.10*

☒ as "Express Mail Post Office to Address"
Mailing Label No. EV327549117US
(mandatory)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.


SignatureDate: July 29, 2003JENNIFER RASHKIN

(type or print name of person certifying)

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

1. That the following culture(s) referred to in the specification of this application have been deposited:

PTA-4485

Accession number

PTA-4486

Accession number

Accession number

Accession number

(check appropriate item below)

[] after the U.S. filing date of this application and proof that the culture(s) identified above is(are) the same culture(s) described in the application as filed is attached.

FOOD INDUSTRY RESEARCH AND DEVELOPMENT INSTITUTE

Name of depository

P.O. BOX 246 HSINCHU 300 TAIWAN, R.O.C.

Address of depository

(complete a, b or c below)

c. [] a competent third party.

(Statement of Biological Culture Deposit--page 2 of 4 9-25

5. That, with respect to the permanence of the culture(s) deposit:

(complete a, b, or c)

- a. ☒ the depository is an official depository, in accordance with the Budapest Treaty for the above deposited culture(s).
- b. ☐ the depository affords permanence of the deposit for at least 30 years or at least 5 years after the most recent storage request, whichever is longest.
- c. ☐ evidence that permanent availability of the microorganism is assured is provided in the form of the attached copy of the contract with the above-mentioned depository with respect to the deposited culture(s).

I state that should the microorganism(s) mutate, become nonviable or be inadvertently destroyed, applicants will replace such microorganism(s) for at least 30 years from the date of the original deposit, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-mentioned application, whichever period is longer.

6. That, with respect to availability of the culture(s), I state that the deposit has been made under conditions of assurance of (a) ready accessibility thereto by the public if a patent is granted whereby all restrictions to the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent (M.P.E.P. 608.01 (p)), and (b) access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. section 1.14 and 35 U.S.C. section 122.

- ☒ Evidence of the accessibility of the culture(s) as set forth above is provided in the form of the attached copy of the contract with the above mentioned depository with respect to the deposited cultures.

July 29, 2003

Date

WILLIAM R. EVANS

(type or print name of person signing)



Signature

P.O. BOX Address of Signatory

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023
REG. NO.: 25, 858 (212) 708-1930

- 7
- ☐ Inventor
☐ Assignee of complete interest
☒ Person authorized to sign on behalf of assignee

(complete the following, if applicable)

(type name of assignee)

Address of assignee

Title of person authorized to sign on behalf of assignee: _____

Assignment recorded in PTO on _____

Reel _____ Frame _____

A "STATEMENT UNDER 37 C.F.R. 3.73(b)" is attached.